New drugs applications

2742. SHRI MUNAVVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) the names of the new drugs for which applications have been received by DCGI during the current year; and

(b) when these applications were received and what is the status of their clearance?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b)The names and status of the new drugs for which the applications have been received by the DCG(I) from January to July, 2003 are given in the statement enclosed.

Statement

New molecule applications received from January to July, 2003

S.No.	Date	New Drug	Status
1.	20.01.03	Indocynain Green	CDL testing
2.	20.01.03	Tadalafil	Clinical Trial report awaited
3.	24.01.03	Modafinil	Referred to experts
4.	28.01.03	Torsamide	Approved*
5.	04.02.03	Cladribine	Referred to experts
6.	04.02.03	Zonisamide	Referred to Experts
7.	05.02.03	Rosuvastatin	Clinical Trial report received
8.	11.02.03	Levosiminden	Information asked
9.	17.02.03	Duloxetin HCI	Referred to experts
10.	17.02.03	Alfuzosin	Clinical Trial asked
11.	24.02.03	Teriparatide	Referred to Experts
12.	25.02.03	Tritropium	Approved*
13.	26.02.03	Ezetimibe	Clinical Trial, CDL
14.	11.03.03	Gadovarsitamide	Approved*
15.	20.03.03	Dlflucortlan Cream	Referred to Experts
16.	28.03.03	Miglitol	Clinical Trial asked

S.No.	Date	New Drug	Status
17.	16.04.03	Oxycodon	Information asked
18.	16.04.03	Aceclofenac	Clinical Trail granted
19.	22.04.03	Rebamipide	Information asked
20.	24.04.03	Acitretin	Clinical Trial granted
21.	24.04.03	Etoricoxib	Clinical Trial granted
22.	02.05.03	Nuvaring ring	Referred to Experts, ICMR
23.	21.05.03	Lacitol Monohydrat	Information asked
24.	26.05.03	Nitazoxanide	Information asked
25.	23.06.03	Residronate sod.	Referred to Experts
26.	23.06.03	Geftinib	Under Process
27.	04.07.03	Seratrodost	Under Process
28.	08.07.03	Eplerenone	Under Process
29.	17.07.03	Orlistat	Under Process
30.	28.07.03	Edaravone	Under Process

*Tritropium-Approved in April, 2003

*Torsamide and Gadovarsitamide-Approved in June, 2003.

Registration of Chinese drugs

2743. SHRI MUNAVVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) the details of the applications alongwith names of the drugs, received from the Chinese manufacturers for registration;

(b) the names of the drugs and manufacturers to whom registration has been granted;

(c) whether the DCGI office has conducted any inspection of all these units;

(d) whether there is any assurance that good quality material would be supplied by the Chinese manufacturers; and

(e) if so, how Government propose to monitor the quality?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b) The requisite information as on 15th July, 2003 can be obtained from Directorate General of Health Services website www.cdsco.nic.in